

### REMARKS

Claims 1-19, and 21-32 are pending in this application, and claim 28 is withdrawn.

Applicants thank the Examiner for allowance of claims 6-9 and 17-19.

#### Rejections based on Neiimeister et al.

Claims 1, 2, 15, 16, 29, and 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Neiimeister et al. (U.S. Patent No. 4,560,352). Applicants respectfully traverse this rejection. The present invention, as recited in claim 1, is related to a system for percutaneous delivery of bone cement during a surgical procedure, and in particular, a plunger system of the delivery system. The plunger assembly includes a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft. The plunger assembly also includes a dispenser hub assembly around the shaft. The dispenser hub assembly has a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar. Further, the plunger assembly includes a hollow tube filled with bone cement for use during the surgical procedure having a first end and a second end, the first end of the hollow tube adapted to be removably attached to the dispenser hub assembly, wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube.

Neiimeister et al. is related to a dispenser for metering dental compositions. The grounds of rejection state that Neiimeister et al. disclose a plunger assembly having a shaft 46, a handle 51 attached to a first end of the shaft, and a dispenser hub assembly including a collar 45 and a handle 61 attached to the collar. Further, the grounds of rejection allege that Neiimeister et al. disclose a hollow tube or casing 4.

Applicants respectfully submit that one of ordinary skill in the art would not consider finger 51 (see col. 4, lines 2-10) as a "handle" attached to a shaft. Rather finger 51 is used as a guide in conjunction with longitudinal slot 52 to guide spindle 46 such that the spindle is secured against rotation relative to the sleeve 41 (Id). By its ordinary definition, a "handle" is part that is designed especially to be grasped by the hand (see <http://www.m-w.com/dictionary/handle>).

Indeed, the Neiimeister et al. device is based on a "one hand" operated dispenser to overcome the problems of the prior art as discussed in the Description of the Invention at col. 1. In operation, a right hand is used such that handle 61 rests against the ball of the thumb and is surrounded by the middle, fourth, and little fingers. The index finger and thumb are used to rotate casing 44 as the device is held in this manner. As such, Neiimeister et al. actually *teaches away* from a handle on a shaft since a two-handed operation would be needed. Accordingly, independent claims 1, as well as independent claims 29 and 30 which also include this feature distinguish from the Neiimeister et al. device. Claims 2, 15, and 16 are allowable over Neiimeister et al. at least based in their dependence on claim 1.

#### Rejections based on Preissmen

Claims 1, 2, 4, 5, 10, 15, 16, 29, and 30 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,383,190 to Preissman. Applicants respectfully traverse this rejection.

Applicants note that while Preissman was previously used in the rejection of the claims in the February 16, 2006 Office Action, in this Office Action, the Examiner uses a new grounds of rejection, based on the Preissman device disclosed in Figure 11.

Preissman is related to a pressure applicator for delivering implant material during surgery for the repair of hard tissue. The grounds of rejection state that Preissman disclose a shaft 76' with handle 72 attached to the shaft, a dispenser hub assembly having a collar and a handle 75, and a hollow tube 74' removeably engaged with the dispenser hub assembly. These features are recited in independent claims 1, 29, and 30.

As noted above, the grounds of rejection allege that item 74' is a hollow tube that is removeably attached to the dispenser hub assembly. However, from the disclosure of Preissman, item 74' (or 74 in Figure 10) is a column that is threaded and mates with column 76 (the shaft as characterized in the grounds of rejection) (see col. 12, lines 13-26 and Figure 11). Therefore, item 74' in the Preissman device is part of the hub assembly and not a removable attachable hollow tube.

Applicants further note that while Preissman discloses a path for delivering implant material, there is no indication that this path is removably attachable, particularly when the shaft is attached to the dispenser hub assembly as recited in claim 1. An advantage of having a hollow tube being removably attached to a dispenser hub is that the hollow tube can be directly removed without having to first unthread the shaft. Therefore, Applicants respectfully submit that the claims distinguish from Preissman.

Rejections based on Pierson et al.

Claims 1, 2, 10, 15, 16, 29, and 30 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,571,992 to Pierson et al. Applicants respectfully traverse this rejection.

Pierson et al. disclose a dispensing syringe. The grounds of rejection state, *inter*

*alia*, that Pierson et al. disclose a dispenser hub assembly having a collar 60 and a hand grip 51 attached to the collar 60. This feature is recited in independent claims 1, 29, and 30. However, Applicants respectfully submit that there is no disclosure or suggestion that hand grip 51 is attached to collar 60. Rather "handle" 51 is part of gripping assembly 40. Gripping assembly 40 mates with a threaded section of barrel 20 (see col. 3, lines 14-31). An extruding section of barrel 20 (threaded portion 34) mates with nut 60 (alleged by the grounds of rejection as the collar) (see col. 3, lines 46-51). As such, there is no attachment between the gripping assembly 40 and nut 60. Rather, they are both individually secured to the barrel 20. Accordingly, claims 1, 2, 10, 15, 16, 29, and 30 distinguish from Pierson et al.

#### 35 U.S.C. § 103(a) Rejections

Claims 11, 12, and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Preissman. Claims 13 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Preissman in view of U.S. Patent No. 4,312,343 to LeVeen et al. Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Preissman in view of U.S. Patent No. 5,603,701 to Fischer. Claims 3-5 and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierson et al. in view of Preissman. Claims 12, 13, 31, and 32 stand rejected under 35 U.S.C. § 103(a) as being Pierson et al. in view of LeVeen et al. Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierson et al. in view of Fischer.

Applicants respectfully submit that these claims are allowable at least based on their dependency on their respective independent claims. Discussion of reasons as to why the cited art in these rejections is deficient is discussed above.

Claims 21-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,395,007 to Bhatnagar et al. in view of Preissman. Claims 21-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bhatnagar et al. in view of U.S. Patent No. 5,638,997 to Hawkins et al. Claims 21 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,156,606 to Chin in view of Hawkins et al. Claims 22-25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chin and Hawkins, and further in view of Preissman. Applicants respectfully traverse these rejections.

In order to establish a *prima facie* showing of obviousness under Section 103, the Examiner must set forth three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. See MPEP §§ 706.02(j), 2142 (8th ed., 2nd Rev., 2004). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference (or the references when combined must teach or suggest all of the claim limitations. *Id.*

The only apparent motivation for combining the references above arises from Applicants' disclosure and the claimed invention itself, which constitutes impermissible hindsight motivation and cannot be relied upon as a reason to combine references. See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

With respect to the rejections based on Bhatnagar et al. and Hawkins et al., and Chin and Hawkins et al., Applicants first note that the Examiner has not met the standard for an obviousness rejection since the Examiner provides *no motivation* to

combine the references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Here, the Examiner fails to show a motivation for combining the references, and only alleges that they are functionally equivalent. Being functionally equivalent perhaps only satisfies the second part of the test as described above. The Examiner does not provide the motivation for the combination as in the first part of the test. Nor has the Examiner clearly shown how, when combined, the references teach or suggest all of the claim limitations.

As such, Applicants respectfully submit that these rejections are improper. Should the Examiner not withdraw the rejections, the Examiner is kindly requested to provide the motivation for their combination as well as further define how each of the references teach the "recited" features of the claims.

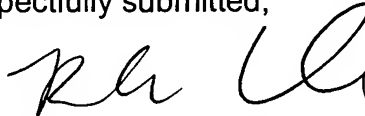
In view of the foregoing, Applicants respectfully submit that the cited references do not teach or suggest the claimed subject matter and request withdrawal of the rejections of the claims under Section 103.

## Conclusion

Applicant respectfully submits that the claims of the present invention define patentable subject matter and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the below listed telephone number.

It is believed that no fee is required for the present amendment. In the event that a fee is required, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Respectfully submitted,



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